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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313 on the date shown below:

August 8, 2005

David Saliwanchik

David R. Saliwanchik, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. UF-T278
Patent No. 6,796,305 B1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Banner *et al.*
Issued	:	September 28, 2004
Patent No.	:	6,796,305
For	:	Ventilator Monitor System and Method of Using Same

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:	**Application Reads:**
Column 3, line 62:	Page 6, line 1:
modem	modern

Patent Reads:	**Application Reads:**
Column 4, line 8:	Page 6, line 15:
modem	modern
Column 6, line 3:	Page 10, line 11:
(SIMY);	(SIMV);
Column 6, line 60:	Page 11, line 24:
at least. one	at least one
Column 7, line 40:	Page 12, line 29:
a-plurality	a plurality
Column 8, line 18:	Page 13, line 33:
attache dot	attached to
Column 8, line 21:	Page 14, line 1:
to, the arm	to the arm
Column 8, line 25:	Page 14, lines 3-4:
data maybe	data may be
Column 8, line 25:	Page 14, line 4:
derived form	derived from
Column 10, line 30:	Page 17, line 25:
the sun of	the sum of
Column 19, line 2, (Claim 1):	Page 2 of Response dated April 21, 2004, Claim 39, line 10:
the signals;	the output signals;

Patent Reads:	**Application Reads:**
Column 19, line 17, (Claim 2):	Page 2 of Response dated April 21, 2004, Claim 40, line 4:
sorting controls,	setting controls,
Column 20, line 30, (Claim 10):	Page 4 of Response dated April 21, 2004, Claim 48, line 1:
wherein comprising:	further comprising:

True and correct copies of the application as filed and the Response dated April 21, 2004 which support the Applicants' assertion of the error on the part of the Patent Office accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

David Saliwanchik

David R. Saliwanchik
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Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRS/hey

Attachments: Certificate of Correction in duplicate;
Copy of Response dated April 21, 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,796,305 B1

DATED : September 28, 2004

INVENTORS : Banner *et al.*

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3,
Line 62, "modem" should read – modern –.

Column 4,
Line 8, "modem" should read – modern –.

Column 6,
Line 3, "(SIMY);" should read – (SIMV); –.

Column 6,
Line 60, "least. one" should read – least one –.

Column 7,
Line 40, "a-plurality" should read – a plurality –.

Column 8,
Line 18, "attache dot" should read – attached to –.

MAILING ADDRESS OF SENDER:
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PATENT NO. 6,796,305
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DATED : September 28, 2004

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Column 8,
Line 21, "to, the arm" should read – to the arm –.

Column 8,
Line 25, "data maybe" should read – data may be –.

Column 8,
Line 25, "derived form" should read – derived from –.

Column 10,
Line 30, "sun of" should read – sum of –.

Column 19,
Line 2, (Claim 1), "the signals;" should read – the output signals; –.

Column 19,
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Column 20,
Line 30, (Claim 10), "wherein comprising:" should read – further comprising: –.

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FORM PTO-1050 (REV. 3-75) UNITED STATES PATENT AND TRADEMARK OFFICE

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PATENT NO. 6,796,305
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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date shown below:

April 21, 2004

David Saliwanchik

David R. Saliwanchik, Patent Attorney

RESPONSE UNDER 37 CFR §1.116
Examining Group 3761
Patent Application
Docket No. UF-T278
Serial No. 09/608,200

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Mital B. Patel
Art Unit	:	3761
Applicants	:	Michael Banner, Neil R. Euliano, Jose Principe, and Paul Blanch
Serial No.	:	09/608,200
Filed	:	June 30, 2000
For	:	Ventilator Monitor System and Method of Using Same

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR §1.116

A Petition and Fee for a three-month Extension of Time through and including April 21, 2004 accompanies this Amendment.

In response to the Office Action dated October 21, 2003, please amend the above-referenced patent application to read as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks/Arguments follow the amendment sections of this paper.

In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

39 (currently amended) A method for monitoring ventilation support for a patient having an airway, wherein said method comprises:

(1) ~~providing~~ utilizing a monitoring system comprising:

(a) a plurality of measuring sensors ~~adapted to~~ that monitor the patient, or ~~to~~ that monitor a breathing circuit coupled to the airway of the patient, each measuring sensor generating an output signal, and

(b) an intelligence system ~~adapted to receive the~~ that receives at least one of the output signals, wherein the intelligence system evaluates at least one output signal to determine the appropriateness of ventilation for the patient;

(2) receiving into the intelligence system at least one of the output signals;

(3) implementing the intelligence system, without clinician input, to evaluate the at least one output signal to determine the appropriateness of ventilation for the patient; and

(4) recommending, without clinician input, a setting for at least one of the plurality of ventilator setting controls based on the evaluation of the at least one output signal by the intelligence system, wherein said setting is appropriate for the patient at that particular time.

40 (previously presented). The method of claim 39, further comprising providing a ventilator adapted to supply a gas to a patient via a breathing circuit in fluid communication with at least one lung of the patient, wherein the ventilator is operatively connected to the intelligence system, and wherein the ventilator includes a plurality of ventilator setting controls, wherein each ventilator setting control controls a parameter relating to the supply of gas from the ventilator to the patient.

41 (previously presented). The method of claim 40, further comprising:

causing the ventilator to generate a ventilator parameter signal indicative of a parameter related to the supply of gas from the ventilator to the patient; and

providing the ventilator parameter signal to the intelligence system, wherein the intelligence system evaluates the at least one output signal and the ventilator parameter signal to determine the appropriateness of ventilation.

42 (previously presented). The method of claim 40, further comprising adjusting at least one of the plurality of ventilator setting controls based on the setting determined in the recommending step.

43 (previously presented). The method of claim 39, wherein said output signals are selected from the group consisting of: an exhaled carbon dioxide signal indicative of the exhaled carbon dioxide (ExCO2) level of the exhaled gas expired by the patient within the breathing circuit; a flow rate signal indicative of the flow rate (V) of the inhaled/exhaled gas expired by the patient within the breathing circuit; a pulse oximeter hemoglobin oxygen saturation (SpO2) signal indicative of the oxygen saturation level of the patient; a pressure (P) signal indicative of the pressure of the breathing gas within the breathing circuit; a blood pressure (BP) signal indicative of the blood pressure of the patient; and a temperature (T) signal indicative of the core body temperature of the patient.

44 (previously presented). The method of claim 43, wherein the output signals also include at least one of the group consisting of: an arterial blood gas PaO2 signal; an arterial blood gas PaCO2 signal; and an arterial blood gas pH signal.

45 (previously presented). The method of claim 39, wherein the ventilator parameter signals include at least one of the group consisting of: a minute ventilation (V_E) signal; a ventilator breathing frequency of (f) signal; a tidal volume (V_T) signal; a breathing gas flow rate (V) signal; a pressure limit signal; a work of breathing (WOB) signal; a pressure support ventilation (PSV) signal; a positive end expiratory pressure (PEEP) signal; a continuous positive airway pressure (CPAP) signal; and a fractional inhaled oxygen concentration (FIO2) signal.

46 (previously presented). The method of claim 39, further comprising displaying the recommended settings of the ventilator setting controls.

47 (previously presented). The method of claim 39, wherein the intelligence system comprises a neural network, and wherein recommending the settings of the ventilator setting controls of the ventilator comprises applying at least a portion of the output signals and the ventilator parameter signals to the neural network of the intelligence system to determine the recommended settings of the ventilator setting controls.

48 (previously presented). The method of claim 39, further comprising:

selecting output signals for display; and

displaying the selected output signals in real time.

49 (previously presented). The method of claim 39, further comprising displaying at least one of the recommended ventilator setting control settings.

50 (previously presented). The method of claim 39, wherein the intelligence system is programmed with a set of decision rules.

51 – 62 (cancel).

Remarks

Claims 39-62 were pending in the subject application. By this Amendment, claim 39 has been amended and claims 51-62 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 39-50 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The applicants wish to thank Examiner Patel for the courtesy of the examiner interview conducted with the undersigned on April 20, 2004. The remarks and amendments set forth herein are consistent with the substance of that interview and are believed to address the outstanding issues as discussed during the examiner interview.

The amendments to the claims set forth herein have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 39-62 have been rejected under 35 U.S.C. §102(b) as being anticipated by Biondi *et al.* (U.S. Patent No. 6,158,432). The applicants respectfully traverse this grounds of rejection because the Biondi *et al.* reference does not teach or suggest the applicants' unique method for ventilation monitoring and control. Specifically, Biondi *et al.* does not disclose a system that recommends, without clinician input, a ventilator control setting for a particular patient at that particular time based on the evaluation by an intelligence system of at least one output signal.

The Biondi *et al.* system requires the clinician to select specific ventilator control settings. The Biondi *et al.* system then monitors the performance of the system and, based on simulator algorithms, adjusts the mechanics of the system to effect the directions that were selected by the clinician. The Biondi *et al.* system does not, and cannot, recommend appropriate settings without clinician input to best facilitate patient care. Rather, the Biondi *et al.* system simply tries to carry out the operator's instructions. It is important to recognize that, when the current applicants refer to

"ventilation control settings" they are referring to the settings that, when using the Biondi *et al.* system, must be entered by a clinician.

Please note the following passage in the Biondi *et al.* patent.

> One feature of the ventilator control system **10** is that it can be configured to provide an assisted phase of a breath to the patient **20**. As noted previously, the accumulated volume of gas inhaled by the patient as a result of his spontaneous respiratory muscle activity can be monitored. To accomplish this, the sensor monitoring system **19** measures the flow of gas inhaled by the patient **20** at the beginning of the inspiration phase of the breath and integrates the flow to provide the measured volume. The embedded controller **14** compares the measured volume to a trigger volume set by the clinician **16**, and adjusts the plurality of controls within the pneumatic system **41** when the measured accumulated volume exceeds the trigger volume to provide an assisted phase of a breath. The embedded controller **14** also may adjust the trigger volume dynamically according to measured patient flow and pressure signals indicating the phase of the respiratory cycle. In particular, the embedded controller **14** may increase the trigger volume set by the clinician **16** during periods of the breath where increasing the pressure at the airway of the patient **20** may be induced by changes in the pneumatic system **41**, and not by spontaneous efforts of the patient.

The applicants respectfully submit that the cited passage illustrates important distinctions between the applicants' invention and the Biondi *et al.* system. Please note, for example, the reference to input provided by the clinician (fourth sentence). The simulator disclosed by Biondi *et al.* applies predetermined data structures with predetermined computational instructions to monitor patient ventilation (see for example, col. 13, line 57 through col. 14, line 62). This is in contrast of the current invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH,*

> *supra*; *Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The current applicants respectfully submit that Biondi *et al.* do not disclose the currently-claimed method wherein, without clinician input, an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings. Because Biondi *et al.* do not disclose such a system, the applicants' claims cannot be said to be anticipated by Biondi *et al.*

The distinctions between the current invention and the Biondi *et al.* system are not trivial. In fact, it is precisely the differences between the current invention and Biondi *et al.* that make the current invention particularly advantageous. The Biondi *et al.* system only uses rigid algorithms to try to control the ventilator in order to effect settings entered by the operator. Thus, the care of the patient still depends entirely on judgments made by the operator. In contrast, the subject invention provides a system whereby a multiplicity of variables can be monitored in order to assess the need of a particular patient. These variables, which can include various measures of the patient's physiological response to the ventilator can then be used to achieve the appropriate therapeutic goal. By carefully monitoring the patient in this way, it is now possible to improve and expedite recovery. This is, of course, a tremendous benefit to the patient, the caregiver and the hospital. Such an advantageous method is neither disclosed nor suggested by Biondi *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the prior art rejection based on Biondi *et al.*

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

David Saliwanchik

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Gainesville, FL 32606-6669

DRS/la

VENTILATOR MONITOR SYSTEM AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to the respiratory care of a patient and, more particularly, to a ventilator monitor system that receives a plurality of ventilator support signals indicative of the sufficiency of ventilation support received by the patient, receives at least one ventilator signal indicative of the level settings of the ventilator setting controls of the ventilator, and determines the desired level settings of the ventilator setting controls of the ventilator to provide the appropriate quality and quantity of ventilation support to the patient.

Background:

Mechanical ventilatory support is widely accepted as an effective form of therapy and means for treating patients with respiratory failure. Ventilation is the process of delivering oxygen to and washing carbon dioxide from the alveoli in the lungs. When receiving ventilatory support, the patient becomes part of a complex interactive system which is expected to provide adequate ventilation and promote gas exchange to aid in the stabilization and recovery of the patient. Clinical treatment of a ventilated patient often calls for monitoring a patient's breathing to detect an interruption or an irregularity in the breathing pattern, for triggering a ventilator to initiate assisted breathing, and for interrupting the assisted breathing periodically to wean the patient off of the assisted breathing regime, thereby restoring the patient's ability to breath independently.

In those instances in which a patient requires mechanical ventilation due to respiratory failure, a wide variety of mechanical ventilators are available. Most

modern ventilators allow the clinician to select and use several modes of inhalation either individually or in combination via the ventilator setting controls that are common to the ventilators. These modes can be defined in three broad categories: spontaneous, assisted or controlled. During spontaneous ventilation without other modes of ventilation, the patient breathes at his own pace, but other interventions may affect other parameters of ventilation including the tidal volume and the baseline pressure, above ambient, within the system. In assisted ventilation, the patient initiates the inhalation by lowering the baseline pressure by varying degrees, and then the ventilator "assists" the patient by completing the breath by the application of positive pressure. During controlled ventilation, the patient is unable to breathe spontaneously or initiate a breath, and is therefore dependent on the ventilator for every breath. During spontaneous or assisted ventilation, the patient is required to "work" (to varying degrees) by using the respiratory muscles in order to breath.

The work of breathing (the work to initiate and sustain a breath) performed by a patient to inhale while intubated and attached to the ventilator may be divided into two major components: physiologic work of breathing (the work of breathing of the patient) and breathing apparatus imposed resistive work of breathing. The work of breathing can be measured and quantified in Joules/L of ventilation. In the past, techniques have been devised to supply ventilatory therapy to patients for the purpose of improving patient's efforts to breath by decreasing the work of breathing to sustain the breath. Still other techniques have been developed that aid in the reduction of the patient's inspiratory work required to trigger a ventilator system "ON" to assist the patient's breathing. It is desirable to reduce the effort expended by the patient in each of these phases, since a high work of breathing load can cause further damage to a weakened patient or be beyond the capacity or capability of small or disabled patients. It is further desirable to deliver the most appropriate mode, and, intra-mode, the most appropriate quality and quantity of ventilation support required the patient's current physiological needs.

The early generation of mechanical ventilators, prior to the mid-1960s, were designed to support alveolar ventilation and to provide supplemental oxygen for those patients who were unable to breathe due to neuromuscular impairment. Since that time, mechanical ventilators have become more sophisticated and complicated in response to increasing understanding of lung pathophysiology. Larger tidal volumes, an occasional "sigh breath," and a low level of positive end-expiratory pressure (PEEP) were introduced to overcome the gradual decrease in functional residual capacity (FRC) that occurs during positive-pressure ventilation (PPV) with lower tidal volumes and no PEEP. Because a decreased functional residual capacity is the primary pulmonary defect during acute lung injury, continuous positive pressure (CPAP) and PEEP became the primary modes of ventilatory support during acute lung injury.

In an effort to improve a patient's tolerance of mechanical ventilation, assisted or patient-triggered ventilation modes were developed. Partial PPV support, in which mechanical support supplements spontaneous ventilation, became possible for adults outside the operating room when intermittent mandatory ventilation (IMV) became available in the 1970s. Varieties of "alternative" ventilation modes addressing the needs of severely impaired patients continue to be developed.

The second generation of ventilators was characterized by better electronics but, unfortunately, due to attempts to replace the continuous high gas flow IMV system with imperfect demand flow valves, failed to deliver high flow rates of gas in response to the patient's inspiratory effort. This apparent advance forced patient to perform excessive imposed work and thus, total work in order to overcome ventilator, circuit, and demand flow valve resistance and inertia. In recent years, microprocessors have been introduced into modern ventilators. Microprocessor ventilators are typically equipped with sensors that monitor breath-by-breath flow, pressure, volume, and derive mechanical respiratory parameters. Their ability to sense and transduce "accurately," combined with computer technology, makes the

interaction between clinician, patient, and ventilator more sophisticated than ever. The prior art microprocessor controlled ventilators suffered from compromised accuracy due to the placement of the sensors required to transduce the data signals. Consequently, complicated algorithms were developed so that the ventilators could "approximate" what was actually occurring within the patient's lungs on a breath by breath basis. In effect, the computer controlled prior art ventilators were limited to the precise, and unyielding, nature of the mathematical algorithms which attempted to mimic cause and effect in the ventilator support provided to the patient.

Unfortunately, as ventilators become more complicated and offer more options, the number of potentially dangerous clinical decisions increases. The physicians, nurses, and respiratory therapists that care for the critically ill are faced with expensive, complicated machines with few clear guidelines for their effective use. The setting, monitoring, and interpretation of some ventilatory parameters have become more speculative and empirical, leading to potentially hazardous misuse of these new ventilator modalities. For example, the physician taking care of the patient may decide to increase the pressure support ventilation (PSV) level based on the displayed spontaneous breathing frequency. This may result in an increase in the work of breathing of the patient which may not be appropriate. This "parameter-monitor" approach, unfortunately, threatens the patient with the provision of inappropriate levels of pressure support.

Ideally, ventilatory support should be tailored to each patient's existing pathophysiology, rather than employing a single technique for all patients with ventilatory failure (*i.e.*, in the example above, of the fallacy of using spontaneous breathing frequency to accurately infer a patient's work of breathing). Thus, current ventilatory support ranges from controlled mechanical ventilation to total spontaneous ventilation with CPAP for support of oxygenation and the elastic work of breathing and restoration of lung volume. Partial ventilation support bridges the gap for patients who are able to provide some ventilation effort but who cannot entirely support their

own alveolar ventilation. The decision-making process regarding the quality and quantity of ventilatory support is further complicated by the increasing knowledge of the effect of mechanical ventilation on other organ systems.

The overall performance of the assisted ventilatory system is determined by both physiological and mechanical factors. The physiological determinants, which include the nature of the pulmonary disease, the ventilatory efforts of the patient, and many other physiological variables, changes with time and are difficult to diagnosis. Moreover, the physician historically had relatively little control over these determinants. Mechanical input to the system, on the other hand, is to a large extent controlled and can be reasonably well characterized by examining the parameters of ventilator flow, volume, and/or pressure. Optimal ventilatory assistance requires both appropriately minimizing physiologic workloads to a tolerable level and decreasing imposed resistive workloads to zero. Doing both should insure that the patient is neither overstressed nor oversupported. Insufficient ventilatory support places unnecessary demands upon the patient's already compromised respiratory system, thereby inducing or increasing respiratory muscle fatigue. Excessive ventilatory support places the patient at risk for pulmonary-barotrauma, respiratory muscle deconditioning, and other complications of mechanical ventilation.

Unfortunately, none of the techniques devised to supply ventilatory support for the purpose of improving patient efforts to breath, by automatically decreasing imposed work of breathing to zero and appropriately decreasing physiologic work once a ventilator system has been triggered by a patient's inspiratory effort, provides the clinician with advice in the increasingly complicated decision-making process regarding the quality and quantity of ventilatory support. As noted above, it is desirable to reduce the effort expended by the patient to avoid unnecessary medical complications of the required respiratory support and to deliver the most appropriate mode, and, intra-mode, the most appropriate quality and quantity of ventilation support required the patient's current physiological needs. Even using the advanced

microprocessor controlled modern ventilators, the prior art apparatus and methods tend to depend upon mathematical models for determination of necessary actions. For example, a ventilator may sense that the hemoglobin oxygen saturation level of the patient is inappropriately low and, from the sensed data and based upon a determined mathematical relationship, the ventilator may determine that the oxygen content of the breathing gas supplied to the patient should be increased. This is similar to, and unfortunately as inaccurate as, a physician simply looking at a patient turning "blue" and determining more oxygen is needed.

From the above, in the complicated decision-making environment engendered by the modern venilator, it is clear that it would be desirable to have a medical ventilator monitor system that alerts the clinician of the ventilator's failure to supply the appropriate quality and quantity of ventilatory support and provides advice to the clinician regarding the appropriate quality and quantity of ventilatory support that is tailored to the patient's pathophysiology. Such a ventilatory monitor system is unavailable in current systems.

SUMMARY

In accordance with the purposes of this invention, as embodied and broadly described herein, this invention, in one aspect, relates to a method of monitoring the ventilation support provided by a ventilator that is supplying a breathing gas to a patient via a breathing circuit that is in fluid communication with the lungs of the patient. The ventilator has a plurality of selectable ventilator setting controls governing the supply of ventilation support from the ventilator, each setting control selectable to a level setting. The ventilator support monitor system preferably receives at least one ventilator setting parameter signal, each ventilator setting parameter signal indicative of the level settings of one ventilator setting control, monitors a plurality of sensors, each sensor producing an output signal indicative of a

measured ventilation support parameter, to determine the sufficiency of the ventilation support received by the patient, and determines the desired level settings of the ventilator setting controls in response to the received ventilator setting parameter signal and the output signals. The ventilator support monitor system preferably utilizes a trainable neural network to determine the desired level settings of the ventilator setting controls.

In another aspect, the invention relates to a ventilator support monitor system that supplies a breathing gas to a patient via a breathing circuit in fluid communication with the ventilator and the lungs of a patient. The ventilator preferably has at least one selectable ventilator setting control. The selectable ventilator setting control governs the supply of ventilation support from the ventilator to the patient via the breathing circuit. Each ventilator setting control generates a ventilator setting parameter signal indicative of the current level setting of the ventilator setting.

The ventilator support monitor system has a plurality of sensors and a processing subsystem. The sensors measure a plurality of ventilation support parameters and each sensor generates an output signal based on the measured ventilation support parameter. The processing subsystem is connected to receive the output signal from the sensor and the ventilator setting signal(s) from the ventilator setting control(s). The processor of the processing subsystem runs under control of a program stored in the memory of the processing subsystem and determines a desired level setting of at least one ventilator setting control in response to the ventilator setting parameter signal and the output signal. The processing subsystem of the ventilator preferably utilizes a trainable neural network to determine the desired level settings of the ventilator setting controls.

DETAILED DESCRIPTION OF THE FIGURES

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principals of the invention.

Fig. 1 is a block diagram of one configuration a ventilator monitor system for determining the desired ventilator control settings of a ventilator.

Fig. 2A is a block diagram of one configuration of the ventilator monitor system showing the ventilator providing ventilation support to a patient connected to the ventilator via a breathing circuit.

Fig. 2B is a block diagram of an embodiment of a ventilator monitor system showing the monitor system incorporated into the ventilator.

Fig. 3 is a block diagram of the ventilator monitor system showing a plurality of sensors connected to the processing subsystem.

Fig. 4 is a block diagram of a processing subsystem of the present invention.

Fig. 5 is a block diagram of a feature extraction subsystem of the present invention.

Fig. 6A is a block diagram of one embodiment of the intelligence subsystem of the processing subsystem.

Fig. 6B is a block diagram of a second embodiment of the intelligence subsystem of the processing subsystem.

Fig. 7 is a schematic block diagram of one realization of the system of the invention.

Fig. 8 is a diagram of the basic structure of an artificial neural network having a layered structure.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is more particularly described in the following examples that are intended to be illustrative only since numerous modifications and variations therein will be apparent to those skilled in the art. As used in the specification and in the claims, the singular form "a," "an" and "the" include plural referents unless the context clearly dictates otherwise.

As depicted in Figs. 1 - 3, the ventilator monitor system 10 of the present invention preferably comprises a conventional ventilator 20, a processing subsystem 40, a measuring system, and a display 62. The ventilator 20 supplies a breathing gas to the lungs of the patient P via a breathing circuit 22 that typically comprises an inspiratory line 23, an expriatory line 24, and a patient connection tube 25, all connected by a patient connector 26. The preferred ventilator 20 is a microprocessor-controlled ventilator of a type that is exemplified by a Mallinckrodt, Nelcor, Puritan-Bennet, 7200ae, or a Bird 6400 Ventilator.

To control the delivery of the breathing gas, the preferred ventilator 20 typically has at least one selectable ventilator setting control 30 operatively connected to the processing system 40 for governing the supply of ventilation support provided to the patient P. As one skilled in the art will appreciate, each ventilator setting control 30 is selectable to a desired level setting. Such a ventilator 20 is particularly

useful in controlling the delivery of breathing support so that the quantity and quality of ventilation support coincides with the physiological support needs of the patient P.

In the preferred embodiment, the preferred ventilator 20 can operate selectively in one or more conventional modes, as needed and selected by the operator and/or the processing subsystem 40, including but not limited to: (i) assist control ventilation (ACMV); (ii) sychronized intermittent mandatory ventilation (SIMV); (iii) continuous positive airway pressure (CPAP); (iv) pressure-control ventilation (PCV); (v) pressure support ventilation (PSV); (vi) proportional assist ventilation (PAV); and (vii) volume assured pressure support (VAPS). Further, the level setting of one or more conventional ventilator setting controls 30 of the ventilator 20 (*i.e.*, the intra-mode setting controls of the ventilator 20) may be adjusted, as needed and selected by the operator and/or the processing system 40 in order to maintain the sufficiency of ventilation support delivered to the patient P. The ventilator setting controls 30 of the ventilator 20 include but are not limited to controls for setting: (i) a minute ventilation (Ve) level; (ii) a ventilator breathing frequency (f) level; (iii) a tidal volume (V_T) level; (iv) a breathing gas flow rate (V) level; (v) a pressure limit level; (vi) a work of breathing (WOB) level; (vii) a pressure support ventilation (PSV)level; (viii) a positive end expiratory pressure (PEEP) level; (ix) a continuous positive airway pressure (CPAP) level; and (x) a fractional inhaled oxygen concentration (FIO2) level.

The conventional ventilator 20 contemplated typically has a gas delivery system and may also have a gas composition control system. The gas delivery system may, for example, be a pneumatic subsystem 32 in fluid/flow communication with a gas source 34 of one or more breathing gases and the breathing circuit 22 and in operative connection with the ventilator control settings 30 of the ventilator 20 and the processing subsystem 40. The breathing circuit 22 is in fluid communication with the lungs of the patient P. As one skilled in the art will appreciate, the pneumatic subsystem 40 of the ventilator 20 and the operative connection of that pneumatic

subsystem 40 to the source of breathing gas 34 of the ventilator 20 may be any design known in the art that has at least one actuator (not shown) that is capable of being operatively coupled, preferably electrically coupled, to the ventilator setting controls 30 for control of, for example, the flow rate, frequency, and/or pressure of the breathing gas delivered by the ventilator 20 to the patient P from the gas source 34. Such a pneumatic system 32 is disclosed in U.S. Patents Nos. 4,838,259 to Gluck *et al.*, 5,303,698 to Tobia *et al.*, 5,400,777 to Olsson *et al.*, 5,429,123 to Shaffer *et al.*, and 5,692,497 to Schnitzer *et al.*, all of which are incorporated in their entirety by reference herein and is exemplified by the Mallinckrodt, Nelcor, Puritan-Bennet, 7200ae, and the Bird 6400 Ventilator.

The gas composition control system may, for example, be an oxygen control subsystem 36 coupled to the source of breathing gas 34 and in operative connection to the ventilator setting controls 30 of the ventilator 20 and the processing subsystem 40. The oxygen control subsystem 36 allows for the preferred control of the percentage composition of the gases supplied to the patient P. As one skilled in the art will appreciate, the oxygen control subsystem 36 of the ventilator 20 and the operative connection of that oxygen control subsystem 36 to the pneumatic subsystem 32 and to the source of breathing gas 34 of the ventilator 20 may be any design known in the art that has at least one actuator (not shown) that is capable of being operatively coupled, preferably electrically coupled, to the ventilator setting controls 30 for control of, for example, the percentage composition of the oxygen supplied to the patient P.

The processing subsystem 40 of the ventilator monitor system 10 preferably has an input 44 that is operatively coupled to the ventilator setting controls 30 of the ventilator 20 so that at least one ventilator setting parameter signal 42 may be received by the processing subsystem 40. Each ventilator setting parameter signal 42 is preferably indicative of a setting of a ventilator setting control 30. Thus, the processing system 40 is in receipt of signals 42, preferably continuously, indicative of the current level settings of the ventilator setting controls 30. As one skilled in the art

will appreciate, the current level settings of the ventilator setting controls 30 may be stored in the memory of the processing subsystem 40. In this example, the ventilator setting parameter signals 42 would be input from the memory of the processing subsystem 40 to the processor for continued processing and assessment.

For example, the input of the processing system 40 may receive one or more of the following ventilator setting parameter signals 42: a minute ventilation (V_E) signal indicative of the V_E level set on the ventilator 20; a ventilator breathing frequency (f) signal indicative of the f level set on the ventilator 20; a tidal volume (V_T) signal indicative of the V_T level set on the ventilator 20; a breathing gas flow rate (V) signal indicative of the V level set on the ventilator 20; a pressure limit signal indicative of the pressure limit set on the ventilator 20; a work of breathing (WOB) signal indicative of the WOB level set on the ventilator 20; a pressure support ventilation (PSV) signal indicative of the PSV level set on the ventilator 20; a positive end expiratory pressure (PEEP) signal indicative of the PEEP level set on the ventilator 20; a continuous positive airway pressure (CPAP) signal indicative of the CPAP level set on the ventilator 20; and a fractional inhaled oxygen concentration (FIO2) signal indicative of the FIO2 level set on the ventilator 20.

The measuring system of the monitor system 10 is also operatively connected to the processing subsystem 40. The measuring system senses and measures a plurality of ventilation support parameters which are indicative of the ventilation support provided to the patient P and the physiological condition of the patient P. It is contemplated that the measuring system may comprise at least one sensor 52, and preferably comprises a plurality of sensors 52, for capturing the desired ventilation support data. Each sensor 52 generates an output signal 51 based on the particular measured ventilation support parameter.

In one preferred embodiment shown in Fig. 3, the processing subsystem 30 is shown operatively connected to a flow rate sensor 53, a exhaled CO2 (Ex CO2)

a plurality of sensors such as

sensor 54, a pressure sensor 55, a blood pressure sensor 56, and a SPO2 sensor 57. In this embodiment, it is preferred that the monitor system 10 be responsive to the output signals 51 input into the processing subsystem 40 from, for example: i) the flow rate sensor 53 which is indicative of the flow rate ventilation support parameter of the gas expired/inspired by the patient P within the breathing circuit 22, ii) the gas pressure sensor 55 which is indicative of the pressure ventilation support parameter of the breathing gas within the breathing circuit 22, and iii) the Ex CO2 sensor 54 which is indicative of the exhaled carbon dioxide ventilation support parameter present in the exhaled gas expired by the patient P within the breathing cirucit 22 (*i.e.*, the flow rate output signal 51 generated by the flow rate sensor 53, the gas pressure output signal 51 generated by the gas pressure sensor 55, and the Ex CO2 output signal 51 generated by the Ex CO2 sensor 54). Optionally, the monitor system 10 may be responsive to output signals 51 input into the processing subsystem 40 from the output of the blood pressure sensor 56, which in indicative of the blood pressure ventilation support parameter of the patient P, for example the arterial systolic, diastollic, and mean blood pressure of the patient P, and the SPO2 sensor 57 which is indicative of the hemoglobin oxygen saturation level ventilation support parameter of the patient P (*i.e.*, the blood pressure output signal 51 generated by the blood pressure sensor 56 and the SPO2 output signal 51 generated by the SPO2 sensor 57).

The flow rate sensor 53, the pressure sensor 55, and the Ex CO2 sensor 54 are preferably positioned between the patient connector 26 and the patient connection tube 25. Alternatively, it is preferred that the pressure sensor 55 be located at the tracheal end of the patient connection tube 25. The flow rate, pressure, and Ex CO2 sensors 53, 55, 54 are exemplified by Novametrics, CO_2SMO+ monitor (which has a flow rate, pressure and Ex CO2 sensors). The blood pressure sensor 56 and the SPO2 sensor 57 are exemplified by Dynamap, Inc.'s blood pressure sensor and Novametrics, CO_2SMO+ monitor's SPO2 sensor. The blood pressure sensor 56 and the SPO2 sensor 57 may be attached to a portion of the patient's body to render the requisite measurements. For example, the blood pressure sensor 56, here for example

shown as a blood pressure cuff, is shown attached to the arm of the patient P and the SPO2 sensor 57, which may, for example, be a pulse oximeter, is shown attached to a finger of the patient12 . One skilled in the art will appreciate, the blood pressure data may be derived from the SPO2 sensor 57 which eliminates the need for the blood pressure sensor 56.

Additional standard equipment can include an operator interface 60, which in the preferred embodiment is a membrane keypad, a keyboard, a mouse, or other suitable input device, for providing user inputs of both data and control commands needed to execute the software which implements the various functions of the invention. The operator of the ventilator monitor system 10 of the present invention may provide the processing subsystem 40, via an operator input signal generated by the operator interface 60, with any number of applicable input parameters, such as patient identification information, patient age, patient weight, or other desired patient statistics. It is preferred that the operator input predetermined patient reference data, such as the arterial blood gas ph, the arterial blood gas PaO2, and/or the arterial blood gas PaCO2 of the patient's blood, and/or patient's temperature into the processing subsystem 40 as operator input signals 61 via the operator interface 60. The monitor system 10 may also be responsive to the core body temperature of the patient P which may be input into the processing subsystem 40 as an output signal 51 from a temperature sensor 58 attached to the patient P or as an operator input signal 61 via the operator interface 60.

The processing subsystem 40 preferably comprises a processor 46, for example a microprocessor, a hybrid hardware/software system, controller, or computer, and a memory. The output signals 51 and the ventilation data 72 derived from the output signals 51 are stored in the memory of the processing subsystem 40 at user-defined rates, which may be continuous, for as-needed retrieval and analysis. The ventilator setting signal 42 may also be stored in the memory at a user-defined rate. As one skilled with the art will appreciate, any generated signal may be stored in

the memory at user-defined rates. The memory may be, for example, a floppy disk drive, a CD drive, internal RAM or hard drive of the associated processor 12.

The processing subsystem 40 is responsive to the output signals 51 of the measuring means, the ventilator setting parameter signal(s) 42, and, if provided, the operator input signals 61. The processor 46 runs under the control of a program stored in the memory and has intelligent programming for the determination of at least one desired level setting of the ventilator setting controls 30 based on at least a portion of the output signal 51 from the measuring means, at least a portion of the ventilator setting parameter signal(s) 42 received at the input 44 of the processing subsystem 40, and, if provided, at least a portion of the operator input signals 61.

The desired level settings for the ventilator setting controls 30 of the ventilator 20 may include at least one of the group of: i) a minute ventilation (V_E) level indicative of the desired V_E level to set on the ventilator 20; ii) a ventilator breathing frequency (f) level indicative of the desired f level to set on the ventilator 20; iii) a tidal volume (V_T) level indicative of the V_T level to set on the ventilator 20; iv) a breathing gas flow rate (V) level indicative of the V level to set on the ventilator 20; v) a pressure limit level indicative of the pressure limit level to set on the ventilator 20; vi) a work of breathing (WOB) level indicative of the WOB level to set on the ventilator 20; vii) a pressure support ventilation (PSV) level indicative of the PSV level to set on the ventilator 20; viii) a positive end expiratory pressure (PEEP) level indicative of the PEEP level to set on the ventilator 20; ix) a continuous positive airway pressure (CPAP) level indicative of the CPAP level to set on the ventilator 20; and x) a fractional inhaled oxygen concentration (FIO2) level indicative of the FIO2 level to set on the ventilator 20.

The desired level setting of the ventilator setting controls 30 determined by the processing system 40 of the monitor system 10 may be displayed to the operator via the display. The display of the monitor system 10 preferably comprises a visual

display 62 or CRT, electronically coupled to the processing subsystem 40 for outputting and displaying output display signals generated from the processing subsystem 40.

Still further, the monitor system 10 may have an alarm 21 for alerting the operator of either a failure of the monitor system 10, such as a power failure of loss of signal data input, or an inappropriate setting of a ventilator control 30, such as a level setting of a ventilator setting control 30 currently controlling the delivery of ventilator support to the patient P differing from a recommended desired level setting of the ventilator setting control 30. Preferably, the alarm 21 comprises a visual and/or audio alarm, but any means for alerting the operating clinician know to one skilled in the art may be used. Of course, it is desired to use a backup power supply, such as a battery.

Referring to Figs. 4 and 5, the processing subsystem of the preferred embodiment of the present invention has a means for determining the desired ventilation control settings 30 of the ventilator 20. The determining means preferably comprises a feature extraction subsystem 70 and an intelligence subsystem 80. The feature extraction subsystem 70 has a means for extracting and compiling pertinent ventilation data features from the input of the measuring means (*i.e.*, the output signals 51). In effect, the feature extraction subsystem 70 acts as a preprocessor for the intelligence subsystem 80. An example of the feature extraction subsystem 70 is shown in Fig. 5. Here, a flow rate sensor 53, a gas pressure sensor 55, a SPO2 sensor 57, an Ex CO2 sensor 54, a temperature (T) sensor 58, a blood pressure (BP) sensor 56, of a type described above, and any other desired sensor are operatively connected to the feature extraction subsystem 70 of the processing subsystem 40. Preferably, the flow rate sensor 53, the gas pressure sensor 55, and the Ex CO2 sensor 54 provide the only inputs to the monitor system. The other sensor inputs, and the user input, may be included to increase the reliability and confidence of the determined desired level settings of the controls 30. The monitor system 10 preferably adjusts the extraction of ventilator data 72 as a function of the presence or absence of these optional inputs.

By making the number of inputs optional, which also makes the required number of sensors 52 comprising the measuring system optional, the number of environments in which the ventilator monitor system 10 can be used is increased.

The purpose of the feature extraction subsystem 70 is to calculate and/or identify and extract important variables or features from the output signals 51 produced by the measuring means. For example, from the exemplified required inputs to the feature extraction subsystem 70, *i.e.*, the gas pressure output signal 51, the flow rate output signal 51, and the Ex CO2 output signal 51, a plurality of ventilation data 72 may be derived. The derived ventilation data 72 may comprise: the values of any output signals 51 used, such as, for example, the gas pressure output signal 51, the flow rate output signal 51, and the Ex CO2 output signal 51 output signals 51; the peak inflation pressure (PIP), which is the maximal pressure generated during mechanical ventilation of the lungs; the mean airway pressure (PAW), which is the average positive pressure measured at the airway opening in the patient connection tube 25 or in the breathing circuit 22 over one minute; the positive end expiratory pressure (PEEP), which is the baseline or starting positive pressure prior to mechanical inflation or the positive pressure applied continuously during inhalation and exhalation during spontaneous ventilation; breathing frequency (f), which is the frequency or rate or breathing per minute (the total breathing frequency f_{TOT} is the sum of the mechanical f_{MECH} ventilator preselected frequency and the spontaneous f_{SPON} patient breathing frequency); the tidal volume (V_T) , which is the volume of the breathing gas moving in and out of the lungs per breath ($V_{T\ MECH}$ is the ventilator preselected V_T per breath and $V_{T\ SPON}$ is the inhaled and exhaled volume per breath of the patient); the minute exhaled ventilation (VE), which is the volume of breathing gas moving in and out of the lungs of the patient per minute (V_E is the product of the breathing frequency f and the tidal volume ($V_E = f \times V_T$), and the $V_{E\ TOT}$ is the sum of the ventilator preselected V_E ($V_{E\ MECH}$) and the spontaneous patient V_E inhaled and exhaled per minute ($V_{E\ SPON}$)); the inhalation-to-exhalation time ratio (I:E ratio), which is the ratio of inhalation time to exhalation tiem during mechanical ventilation;

the physiologic dead space volume (V_{Dphys}), which is the volume of gas in the anatomic airway and in ventilated, unperfused alveoli that does not participate in blood gas exhange; the lung carbon dioxide elimination rate (LCO2), which is the volume of CO2 exhaled per breath or per minute (LCO2 is the area under the Ex CO2 and volume curve); the partial pressure end-tidal carbon dioxide level (PetCO2), which is the partial pressure of the exhaled CO2 measured at the end of the exhalation; the cardiac output (CO) of the patient, which is the amount of blood ejected from the heart per minute and which may, for example be derived from the determined LCO2 rate; the respiratory system compliance and resistance; the respiratory muscle pressure, the work of breathing of the patient which may be derived from the determined respiratory muscle pressure; and pressure-volume loops.

Ventilation data 72 may also be derived from the exemplified optional inputs to the feature extraction subsystem 70. From the SPO2 output signal 51, the arterial blood hemoglobin oxygen saturation level and the heart rate may be determined, and the pulsatile blood pressure waveform of the SPO2 output signal 51 may be used to determine arterial blood pressure. Additionally, from the blood pressure output signal 51, the arterial systolic, diastolic and mean blood pressure of the patient P may be determined. Further, from the temperature output signal 51, the core body temperature of the patient may 12 be derived. Still further, from the arterial blood hemoglobin oxygen saturation level and the determined LCO2, the dead space volume may be determined.

The feature extraction subsystem 70 may also receive user input via the operator interface 60 and may receive the ventilator setting parameter signal 42. The ventilation data 72 is preferably compiled in the feature extraction subsystem 70 and a feature vector 74 or matrix is preferably generated which contains all of the ventilation data items used by the monitor subsystem 10 to perform the ventilation support assessment process. The feature vector 74 may be updated at user-defined intervals such as, for example, after each breath or each minute and is output from the